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Stefano Cerbini

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EXAMINER

MOORER, CELENE NICOLE

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,874	<b>Applicant(s)</b> CERBINI, STEFANO	
	<b>Examiner</b> CELENE MOORER	<b>Art Unit</b> 4138	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/2006</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 8/18/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement of 8/18/2006 contains foreign documents, but there are no copies available for review and therefore, these references have been crossed out. All of the other references were considered.

### ***Specification***

2. The disclosure is objected to because its contents appear to be a literal translation into English from a foreign document and is replete with grammatical and idiomatic errors. For example, on page 7 of the specification, the mathematical formula listed at the bottom of the page does not appear to be in the correct equation format. Also, throughout the specification, there are no indentations present to determine where a paragraph begins and ends. Also, the subsections within the specification should be titled appropriately to enable the reader to transition more easily between sections. For example, there should be a subsection title for description of the drawings.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Reference Number 5 in Figure 2. Furthermore, the drawings are objected to because the drawings and reference numbers are difficult to understand.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a central layer", "an inner layer", "an outer layer", "the fiber matrix", "the structure", "the filter layer", "the

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boundary sealing layer", "the boundary layer", "the seal layer", and "the strip" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

5. The drawings are objected to because the drawings and reference numbers are difficult to read.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

6. Claims 27, 29-33, 35-36, and 38-40 are objected to because of the following informalities: There are no periods following each sentence in claims 27, 29-33, and

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38-40; The word "continuous" is misspelled in claims 35 and 36. Appropriate correction is required.

7. Claim 40 is objected to because of the following informalities: In the second and third line of the claim, the claim states, "...a strip, made from the same material than the boundary sealing layer". The use of the word "than" indicates a negative limitation. The claim should be changed to "...a strip, made from the same material as the boundary sealing layer." Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 26-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claim 26 contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not describe the process or mechanism in which the fiber matrix is supported by a strong, cellulose substrate that will enable one of ordinary skill in the art to create this fiber matrix.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. Claims 26-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claim 26, it is unclear as to what is meant by "the structure". The examiner interpreted "the structure" as any component on the mask. As to claims 27 and 39, it is unclear as to what measurement unit was used to determine a unit area in  $\text{g/m}^2$ . In regards to claim 37, it is unclear if the boundary layer and the seal layer is actually referring to the boundary sealing layer as a whole or whether these are three distinct layers. The examiner interpreted the boundary layer and the seal layer as the overall boundary sealing layer. Furthermore, in regards to claim 37, it is unclear if the mask body is referring to the mask and if the filtering material is referring to a layer of the mask that has filtering functions. The examiner interpreted the mask body as the mask and the filtering material as the layer with filtering functions.

12. Claim 26 recites the limitation "the fiber matrix", and "the structure" in the fifth and sixth line of the claim. Claim 28 recites the limitation "the filter layer" in the first line of the claim. Claim 29 recites the limitation "the mask body" and "the filtration layer" in the third and fourth line of the claim. Claim 31 recites the limitation "the filtration layer" in the second line of the claim. Claim 33 recites the limitation "the wearer", "the breathing", and "the mask interior" from the second to the fourth line of the claim. Claim 35 recites the limitation "the relief of the valve seat" in the first and second line of the claim. Claim 36 recites the limitation "the valve flap" in the second line of the claim. Claim 37 recites the limitation "the edges", "the seal", "the boundary layer", "the seal

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layer", "the perimeter of the mask", "the wearer's face", "the mask body", and "the filtering material" from the second to the ninth line of the claim. Claim 40 recites the limitation "the same material", "the nose clip area", "the face", and "the nose portion" from the second to the sixth line of the claim. There is insufficient antecedent basis for all these limitations in the claims.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 26-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 6,584, 976 B2 to *Japuntich et al.* in view of US Patent No. 4,130,487 to *Hunter et al.* in further view of US Patent No. 4,239,716 to *Ishida et al.* in further view of US Patent No. 4,141,703 to *Mulchi* in further view of 5,403,304 to *Ishida*.

The following rejections are made "as understood" in view of the 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejections above.

As to claim 26, *Japuntich* discloses a mask for the protection against biological agents (Column 3, Lines 14-19) consisting in a plurality of layers (Column 6, Lines 41-44), characterized in that at least one of them, having a filtering functions (27).

*Japuntich* does not disclose that at least one of the layers, having filtering functions, is composed of borosilicate micro-glass fibers bound together by a



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vinyl acetate resin, the fiber matrix being supported by a strong, cellulose based, substrate and the structure being treated with a silicone based coating to impart hydrophobic properties.

*Hunter* discloses a filter to be used for gas or liquid (Column 1, Lines 4-5) in which the filtering material may be borosilicate glass fibre held together with an organic binder, and the glass material being impregnated by a synthetic resin binder (Column 1, Lines 32-39). The filter is impregnated and bonded with a synthetic resin (Column 2, Lines 36-41).

*Ishida et. al* discloses a fibrous suspension which can include several types of fibers along with binding agents, e.g. synthetic resin such as vinyl acetate resin (Column 3, Lines 4-13).

*Mulchi* discloses a mask with multiple filter layers in which the filter which can be composed of with glass fibers and cellulose fibers (Column 10, Lines 21-23; 32-34). In addition, the filter can be composed of adsorbent cellulose (Column 10, Lines 62-23).

*Ishida* discloses a device which comprises a filter wherein the membrane can be comprised of an acetate film and a silicone coating formed on the acetate film (Column 7, Lines 13-15, 64-68).

At the time of the invention, it would have been obvious to modify the mask of Japunitch so that at least one of the layers, having filtering functions, is composed of borosilicate micro-glass fibers bound together by a vinyl acetate resin in view of *Hunter* and *Ishida et al.*, the fiber matrix being supported by a

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strong, cellulose based, substrate in view of *Mulchi* and the structure being treated with a silicone based coating in view of *Ishida*. The suggestion/motivation for *Japuntich* in view of Hunter would have been so that the filtering layer is composed of borosilicate micro-glass fibers bound by an synthetic resin binder with this layer providing an adequately supported high efficiency filter medium and withstanding shock pressure loads (*Hunter*, Column 1, Lines 11-18). The suggestion/motivation for *Japuntich* in view of *Hunter* in further view of *Ishida et al.* would have been because *Ishida et al.* discloses that a type of synthetic resin is vinyl acetate resin, therefore, it would have been obvious that the vinyl acetate resin since it is a synthetic resin. The suggestion/motivation for *Japuntich* in view of Hunter in further view of *Ishida et al.* in further view of *Mulchi* would have been so that the filter layer is composed of not only borosilicate micro-glass fibers, but also the fiber matrix is supported by a strong, cellulose based substrate. The suggestion/motivation for *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* would have been in to protect the glass fibers from possible mechanical damage from inside the mask and serving as a moisture vapor trap (*Mulchi*, Column 10, Lines 62-67)

As to claim 27, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* discloses a central layer (27), having filtering functions, is composed of borosilicate micro-glass fibers bound together by a vinyl acetate resin, the fiber matrix being supported by a strong,

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cellulose based, substrate and the structure being treated with a silicone based coating. Furthermore, *Japuntich* discloses an inner layer (29') having a shape retaining function (Column 9, Lines 28-29; Column 20, Lines 54-56) and an outer layer (29) having a covering function (Column 6, Lines 46-49).

As to claim 28, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* does not expressly disclose that the filter layer has thickness ranging between 150 and 400 microns and unit area ranging between 25 and 65g/m<sup>2</sup>. It would have been obvious to one having ordinary skill in the art at the time the filter layer was made to have a thickness ranging between 150 and 400 microns and unit area ranging between 25 and 65g/m<sup>2</sup>, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

As to claim 29, *Japuntich* discloses that the inner layer (29') (Column 9, Lines 28-29), with the function of retaining shape and providing structure to the mask body (Column 11, Lines 46-53) as well as providing support for the filtration layer (Column 6, Lines 46-51), is made from non-woven fabric obtained by polypropylene (Column 11, Lines 38-43).

As to claim 30, *Japuntich* discloses that the inner layer (29') is made from non-woven fabric consisting of polypropylene fibers (Column 11, Lines 38-43).

As to claim 31, *Japuntich* discloses that the outer later (29), having covering function to protect the filtration layer from abrasion, is made from non-woven fabric obtained by polyolefin (Column 6, Lines 46-52).

As to claim 33, *Japuntich* discloses that the mask is equipped with a valve (22) to facilitate the breathing which opens, in response to increased pressure, when the wearer exhales, allowing air to be rapidly evacuated from the mask interior, and which closes during inhaling (Column 6, Lines 8-11).

15. Claims 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 6,584, 976 B2 to *Japuntich et al.* in view of US Patent No. 4,130,487 to *Hunter et al.* in further view of US Patent No. 4,239,716 to *Ishida et al.* in further view of US Patent No. 4,141,703 to *Mulchi* in further view of 5,403,304 to *Ishida* in further view of US Patent No. 6,534,296 B1 to *Baumann et al.*

The following rejections are made “as understood” in view of the 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejections above.

As to claim 32, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* disclose all of the limitations of claim 27, except, they do not expressly disclose that the outer layer (29) is made from meltdown polypropylene. However, *Japuntich* discloses that the outer layer (29) (Column 9, Lines 28-29) can be made from melt-blown microfibers (Column 20, Lines 43-45).

*Baumann* discloses a mask comprising a resilient member Column 1, Lines 18-20) in which polymers are used for forming fibers for the construction of

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the resilient member (Column 5, Lines 45-48). *Baumann* further discloses that a preferred polymer for melt-blown microfibers is polypropylene (Column 5, Lines 52-54).

At the time of the invention, it would have been obvious to one of ordinary skill in the art that the outer layer as disclosed in *Japuntich* is made from meltblown polypropylene fibers. The suggestion/motivation would have been because meltblown polypropylene is a preferred polymer for melt-blown microfiber as disclosed by *Baumann*.

16. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 6,584, 976 B2 to *Japuntich et al.* in view of US Patent No. 4,130,487 to *Hunter et al.* in further view of US Patent No. 4,239,716 to *Ishida et al.* in further view of US Patent No. 4,141,703 to *Mulchi* in further view of 5,403,304 to *Ishida* in further view of US Patent Des 347,299 to *Bryant et al* in further view of US Patent No. 7,188,622 B2 to *Martin et al.*

The following rejections are made "as understood" in view of the 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejections above.

As to claim 34, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* disclose all of the limitations of claim 33. *Japuntich* further discloses that the valve (22) comprises a valve seat (30) over which is secured a valve cover (54), carrying apertures (53) (Column 7, Lines 39-43). In regards to the valve cover being raised, *Japuntich* discloses that the valve cover has a configuration similar to US Patent Design 347,299 to

*Bryant et al* (Column 5, Lines 43-45). As seen by Figures 1 and 3 of this design patent, it is obvious that the valve cover is also raised.

As to claim 35, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* in further view of *Bryant* disclose all of the limitations of claim 34, however, they do not disclose that the relief of the valve seat owns a concave surface wherein a continuous, cylinder shaped plastic lays all along the surface of the relief.

*Martin* discloses a filtering face mask with a valve and a valve seat similar to the design of *Japuntich* (Column 2, Lines 48-62). *Martin* further discloses that the relief of the valve seat (29) owns a concave surface (Column 9, Lines 23-24, 29-33) wherein a continuous cylinder shaped material lays along the surface of the relief (Column 9, Lines 23-24, 29-33; Column 8, Lines 52-54, 59-61). *Martin* does not expressly disclose that the continuous cylinder shaped plastic lays along the surface of the relief. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a continuous cylinder shaped plastic lay along the surface of the relief, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* in further view of *Bryant* in

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further view of *Martin* so that the relief of the valve seat owns a concave surface wherein a continuous, cylinder shaped plastic lays all along the surface of the relief. The suggestion/motivation would have been in order to provide a durable seal during inhaling to prevent contamination.

As to claim 36, *Martin* further discloses that the valve flap is round shaped (Figure 3) and the continuous, cylinder shaped plastic is an O-ring (Column 9, Lines 13-14) lays all over the circumference of the relief (Column 9, Lines 23-24, 29-33; Column 8, Lines 52-54, 59-61). *Martin* does not expressly disclose that the relief of the valve is circular. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a continuous cylinder shaped plastic lay along the surface of the relief, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

17. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 6,584, 976 B2 to *Japuntich et al.* in view of US Patent No. 4,130,487 to *Hunter et al.* in further view of US Patent No. 4,239,716 to *Ishida et al.* in further view of US Patent No. 4,141,703 to *Mulchi* in further view of 5,403,304 to *Ishida* in further view of US Patent No. 5,143,061 to *Kaimer*.

The following rejections are made "as understood" in view of the 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejections above.

As to claim 37, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* disclose all of the limitations of claim 26, except, they do not expressly disclose that the mask is equipped, on the edges, with a boundary sealing layer to improve the seal; the boundary layer is applied along the perimeter of the mask, starting from the side joins; the seal layer tightly fits over the wearer's face adapting to any face shape; that ensures a leak free contact to the wearer's face, without pin holes and distortions which would allow contaminants to pass through the mask body without being removed by the filtering material.

*Kaimer* discloses a face mask with a rubber seal (18) that is secured to the peripheral edge of the mask and adapted to occupy the open spaces between the face of a subject and the peripheral edge of the mask along the upper half of the mask (Column 1, Lines 52-58). The seal also serves to prevent leakage in the mask which is most likely the greatest discomfort to the patient (Column 2, Lines 38-41). Furthermore, the material of the seal provides a comfortable fit in the areas where there is already a close fit between the face and upper portion of the edge (Column 2, Lines 68; Column 3, Lines 1-4).

At the time of the invention, it would have been obvious to modify *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* in further view of *Kaimer* so that the mask is equipped, on the edges, with a boundary sealing layer to improve the seal; the boundary layer is applied along the perimeter of the mask, starting from the side joins; the



seal layer tightly fits over the wearer's face adapting to any face shape; that ensures a leak free contact to the wearer's face, without pin holes and distortions which would allow contaminants to pass through the mask body without being removed by the filtering material. The suggestion/motivation would have been in order to provide the mask with additional sealing means to ensure that the wearer is well protected from any contaminants from entering the mask along with ensuring a comfortable fit.

18. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 6,584,976 B2 to *Japuntich et al.* in view of US Patent No. 4,130,487 to *Hunter et al.* in further view of US Patent No. 4,239,716 to *Ishida et al.* in further view of US Patent No. 4,141,703 to *Mulchi* in further view of US Patent No. 5,403,304 to *Ishida* in further view of US Patent No. 5,143,061 to *Kaimer* in further view of US Patent No. 5,910,567 to *Tanaka et al.*

The following rejections are made "as understood" in view of the 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejections above.

As to claim 38, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* in further view of *Kaimer* disclose all of the limitations of claim 37, except they do not expressly disclose that the boundary sealing layer is made from natural rubber latex applied in some 2mm thickness and in unit area ranging between 200 and 400 g/m<sup>2</sup>. However, *Kaimer* does disclose that the material of the boundary sealing layer is made from foam rubber (Column 2, Lines 68; Column 3, Lines 1-4).

Furthermore, *Tanaka* discloses that natural rubber latex is commonly used for a foam product such as foam rubber (Column 1, Lines 16-19).

At the time of the invention, it would have been obvious to one of ordinary skill in the art that the material sealing layer is made a natural rubber latex resin since foam rubber consists of natural rubber latex.

As to claim 39, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* in further view of *Kaimer* disclose all of the limitations of claim 37. *Kaimer* further discloses that the sealing layer is comprised of foam rubber (Column 2, Lines 68; Column 3, Lines 1-4).

*Tanaka* discloses that natural rubber latex is commonly used for a foam product such as foam rubber (Column 1, Lines 16-19).

At the time of the invention, it would have been obvious to one of ordinary skill in the art that the material sealing layer is made a natural rubber latex resin since foam rubber consists of natural rubber latex.

*Kaimer* does not expressly disclose that the boundary sealing layer is made from natural rubber latex applied in some 2 mm thickness and in unit area ranging between 200 and 400 g/m<sup>2</sup>. It would have been obvious to one having ordinary skill in the art at the time that the boundary sealing layer was made from natural rubber latex applied in some 2 mm thickness and in unit area ranging between 200 and 400 g/m<sup>2</sup>, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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19. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 6,584,976 B2 to *Japuntich et al.* in view of US Patent No. 4,130,487 to *Hunter et al.* in further view of US Patent No. 4,239,716 to *Ishida et al.* in further view of US Patent No. 4,141,703 to *Mulchi* in further view of US Patent No. 5,403,304 to *Ishida* in further view of US Patent No. 6,125,849 to *Williams et al.* in further view of US Patent No. 7,371,464 B2 to *Sherman et al.*

The following rejection is made “as understood” in view of the 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejections above.

As to claim 40, *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* disclose all of the limitations of claim 26, however, they do not expressly disclose adjoining a boundary sealing layer, a strip, made from the same material than the boundary sealing layer, is applied in the nose clip area; the strip makes the mask more comfortable to wear and, further on, improves the seal between the mask and the face at the nose portion wherein the deformations and plies may normally be present.

*Williams et al.* discloses a mask with a design configuration similar to the mask disclosed by *Japuntich* with multiple layers (Figure 1 and 2; Column 3, Lines 23-25). *Williams* further discloses that the mask adjoining a boundary sealing layer (outer surface of either the inner cover web 26 or outer cover web 23), a strip (29) (Column 3, Lines 61-65) is applied to the nose clip area (Column 3, Lines 61-65); *Williams* does not expressly disclose that the strip makes the mask more comfortable to wear and further on, improves the seal between the

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mask and the face at the nose portions wherein the deformation and plies may normally be present, however, it is obvious that the strip is capable of performing these functions since the strip can be placed on a layer of the mask (Column 3, Lines 54-57), thus it must be able to provide a comfortable fit, and improve the seal between these layers that are situated on the mask and face at the nose portions. *Williams* does not expressly disclose that the strip is made from the same material as the boundary sealing layer, however, *Williams* does disclose that the boundary sealing layer can be comprised of non-woven fibrous materials (Column 5, Lines 24-26) and that the strip is comprised of foam (Column 3, Lines 27-28).

*Sherman* discloses several types of polymeric substrate materials and indicates that some polymeric materials are foams, or non-woven fibers.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art that foam or a nonwoven fiber can be used as the material for the strip since foam is a polymeric material. Therefore, the strip could be made of the same material as the boundary sealing layer.

At the time of the invention, it would have been obvious to modify *Japuntich* in view of *Hunter* in further view of *Ishida et al.* in further view of *Mulchi* in further view of *Ishida* in further view of *Williams* in further view of *Sherman* so that adjoining a boundary sealing layer, a strip, made from the same material than the boundary sealing layer, is applied in the nose clip area; the strip makes the mask more comfortable to wear and, further on, improves the seal between

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the mask and the face at the nose portion wherein the deformations and plies may normally be present. The suggestion/motivation would have been in order to provide an additional sealing layer for the mask to provide multiple functions such as comfort and seal durability to prevent contaminants from entering the mask.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELENE MOORER whose telephone number is (571)270-7411. The examiner can normally be reached on M-F 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on (571)272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M./  
Examiner, Art Unit 4138

/Melba Bumgarner/  
Supervisory Patent Examiner

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